

Ecological Risk Assessments

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Objectives

- Provide a basic understanding of the EPA eight-step ERA process
- Familiarize audience with the CNO ERA policy
- Show how the EPA eight-step process fits into the Navy tiers
- Using a Navy case study, demonstrate how the EPA process can help an ERA become more focused and effective

Ecological Risk Assessment (ERA) Guidance for Superfund:

*Process for Designing and
Conducting Ecological Risk
Assessments*

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Environmental Response Team

Topic Overview

- EPA Eight-Step Guidance

- Navy Policy

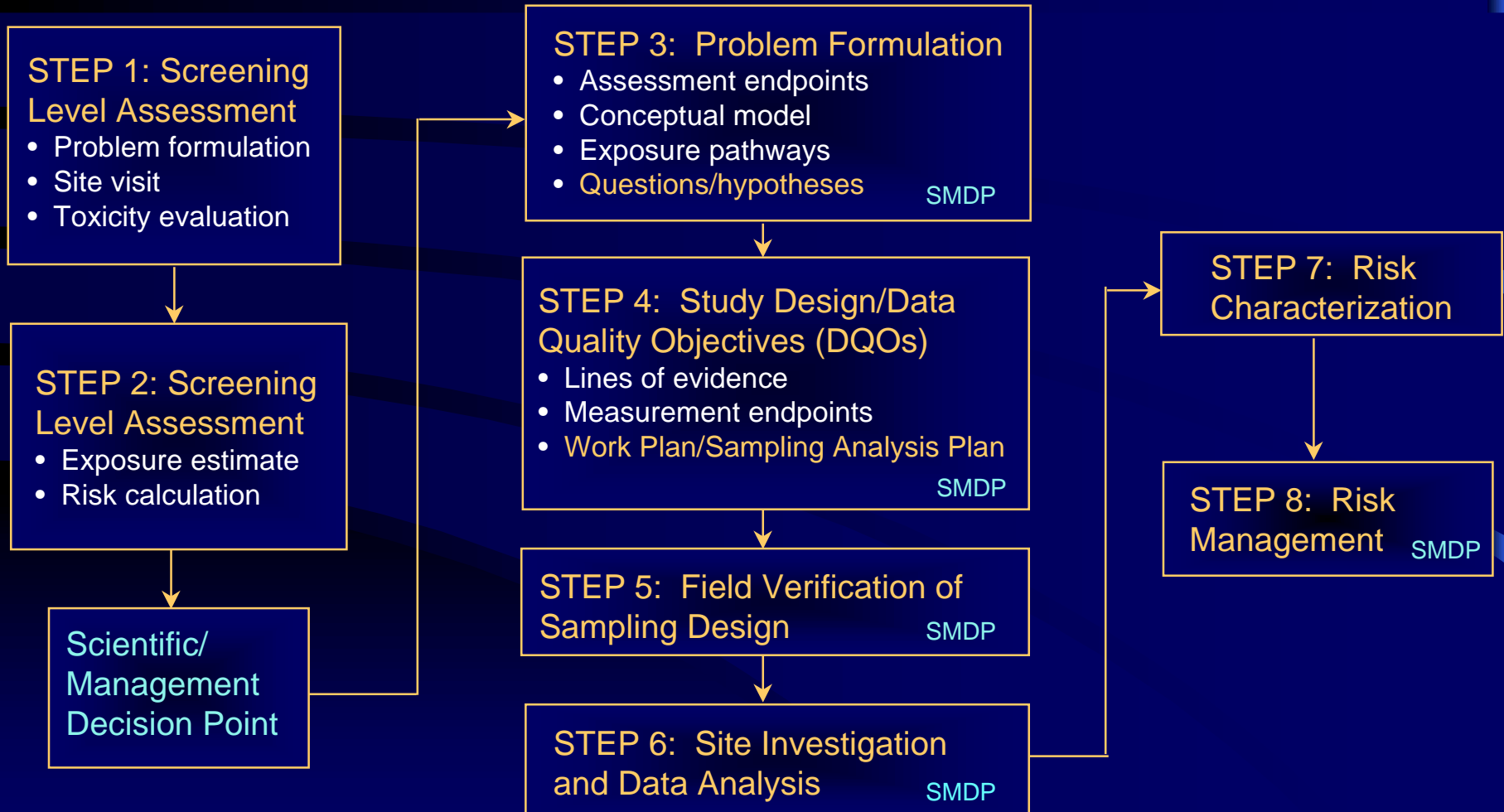
- Case Study

- EPA Eight-Step
Guidance

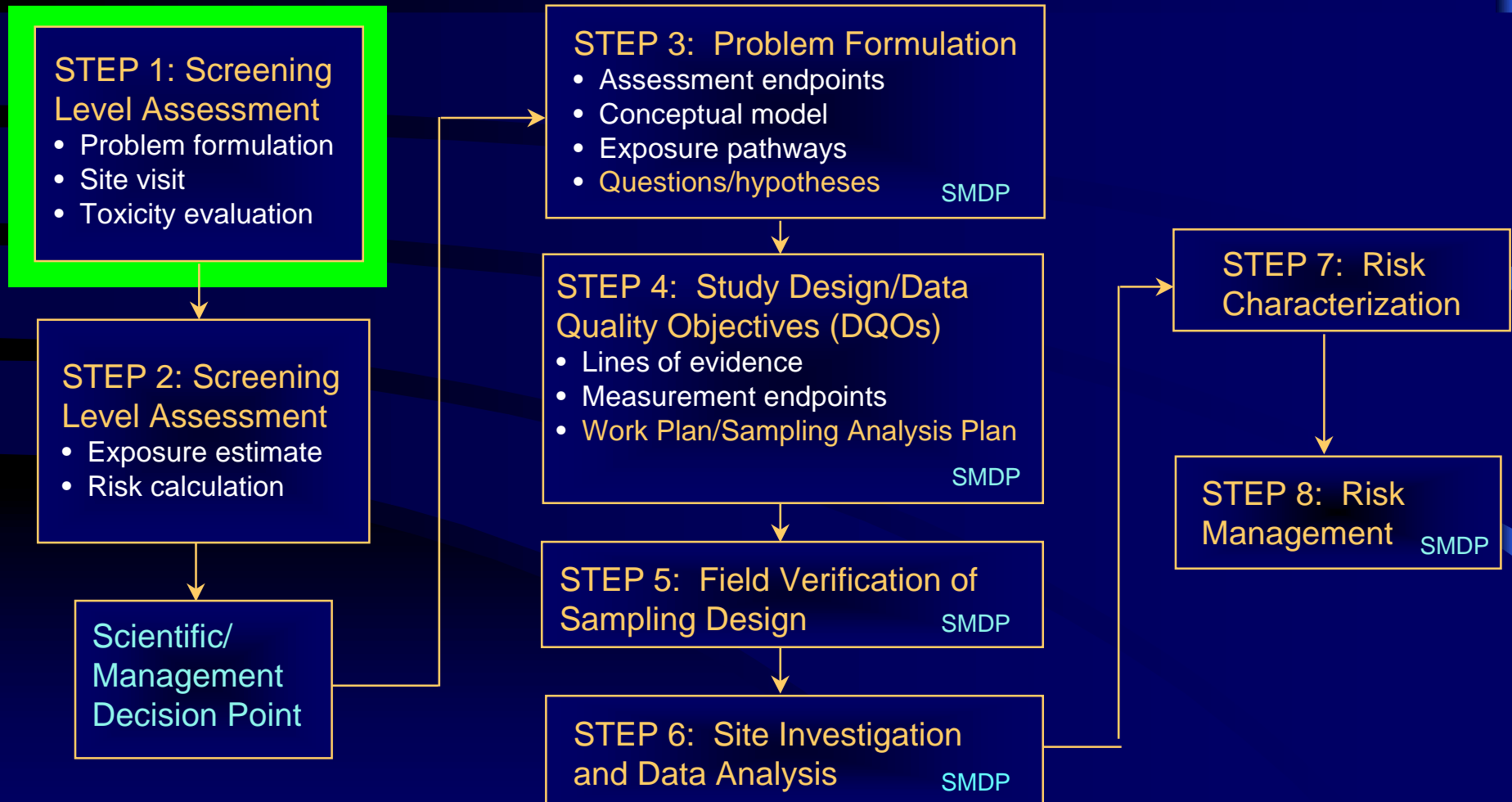
Ecological Risk Assessment: Definition

- The process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors

Eight-Step EPA Superfund Ecological Risk Assessment Guidance



Eight-Step EPA Superfund Ecological Risk Assessment Guidance



Step 1: Screening Level Assessment

Problem Formulation

- Environmental Settings and Contaminants
- Contaminant Fate and Transport
- Ecotoxicity and Receptors
- Complete Exposure Pathways
- Assessment and Measurement Endpoints

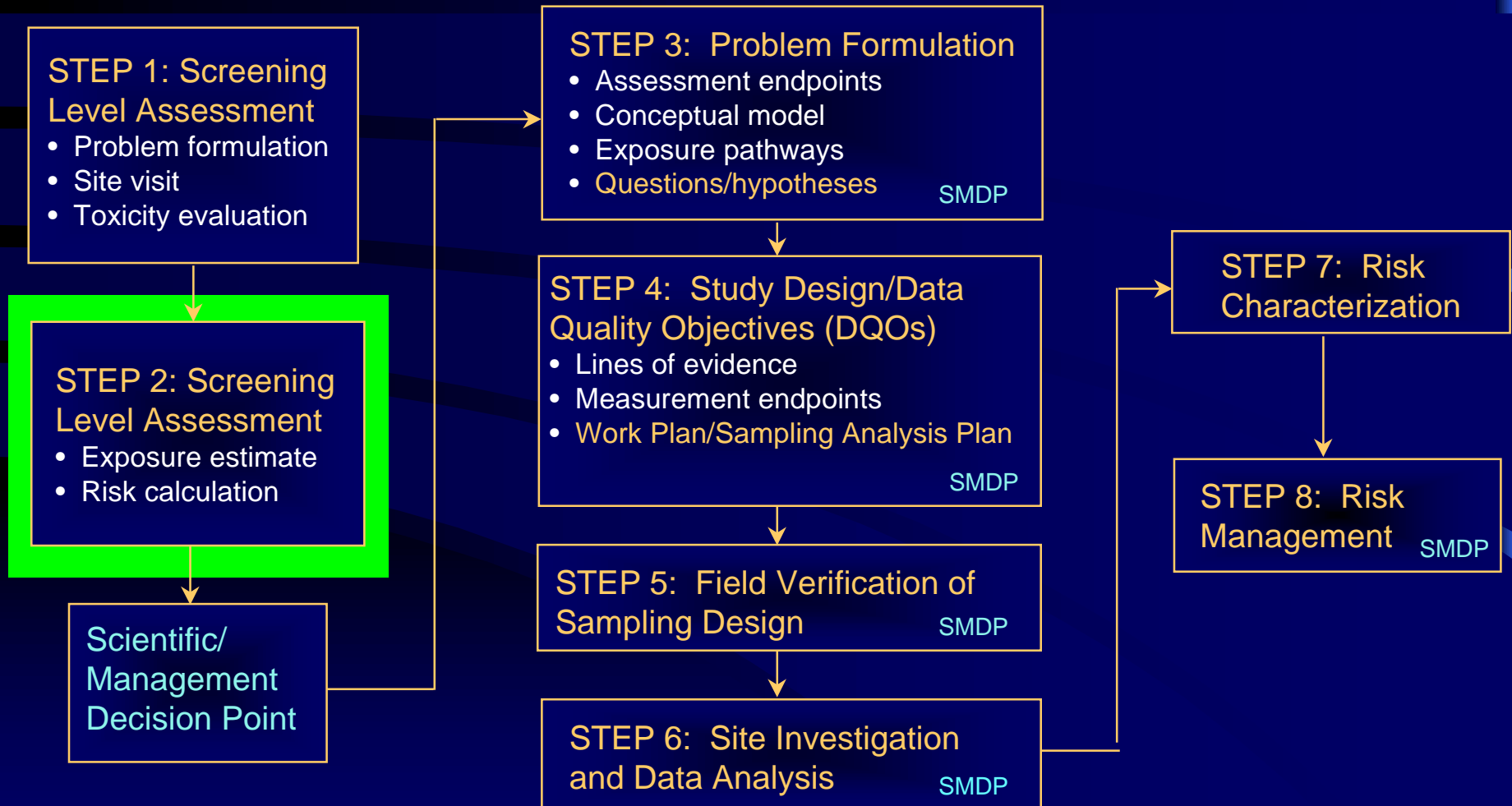
Step 1: Screening Level Assessment

Ecological Effects Evaluation

■ Preferred Toxicity Data

- NOAEL vs. LOAEL
- Exposure duration
- Exposure route
- Field vs. laboratory
- *Dose conversions (if necessary)*
- *Uncertainty assessment (qualitative)*

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Step 2: Screening Level Assessment

Exposure Assessment

■ Exposure Parameters

- Area use factor
- Bioavailability
- Life stage
- Body weight and food ingestion rate
- Bioaccumulation
- Dietary composition

■ Uncertainty Assessment

Step 2: Screening Level Assessment

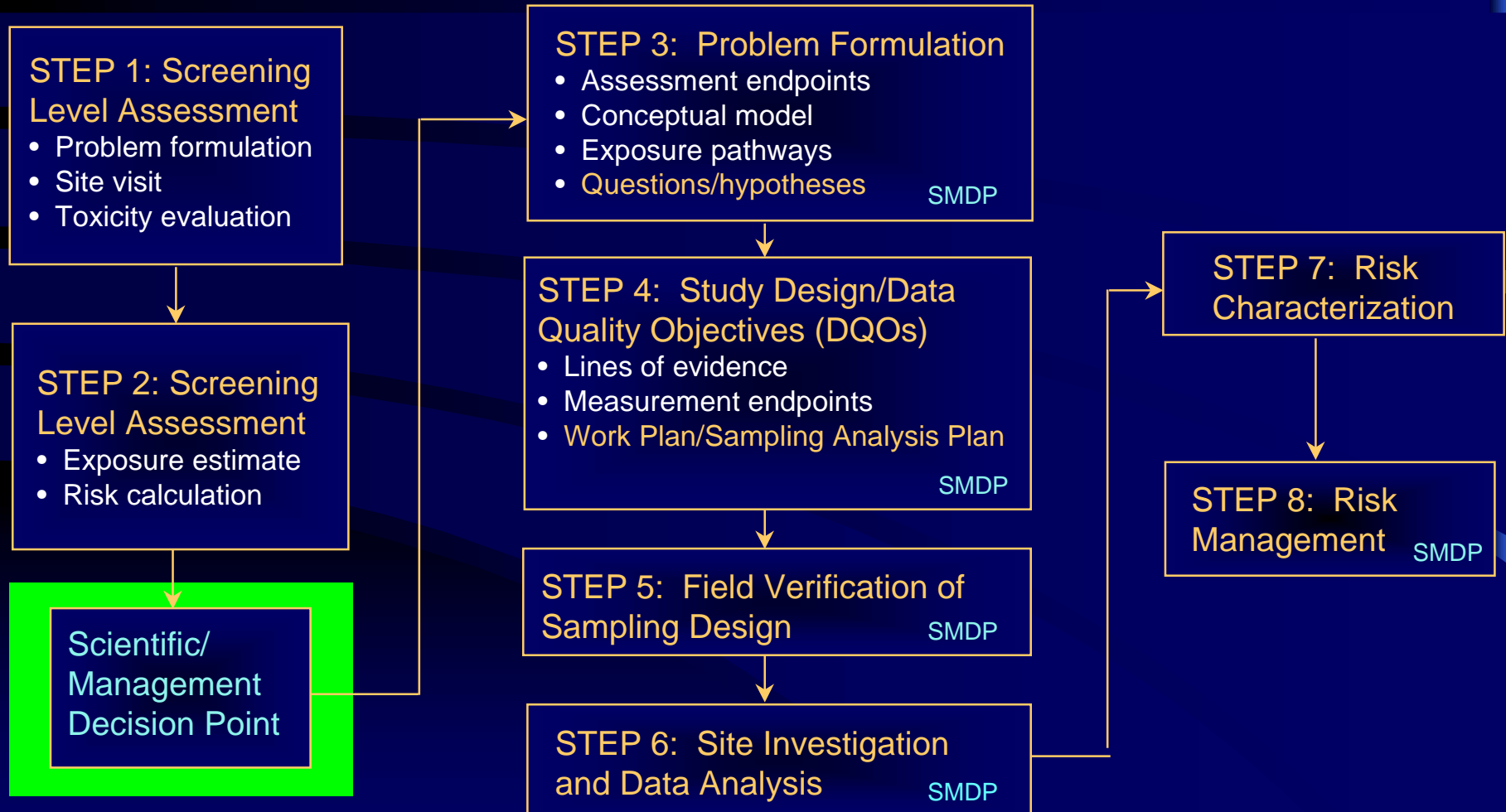
Risk Calculation

$$HQ = \frac{DOSE}{NOAEL}$$

or

$$HQ = \frac{EEC}{NOAEL}$$

Eight-Step EPA Superfund Ecological Risk Assessment Guidance



Scientific/Management Decision Point (SMDP) Definition

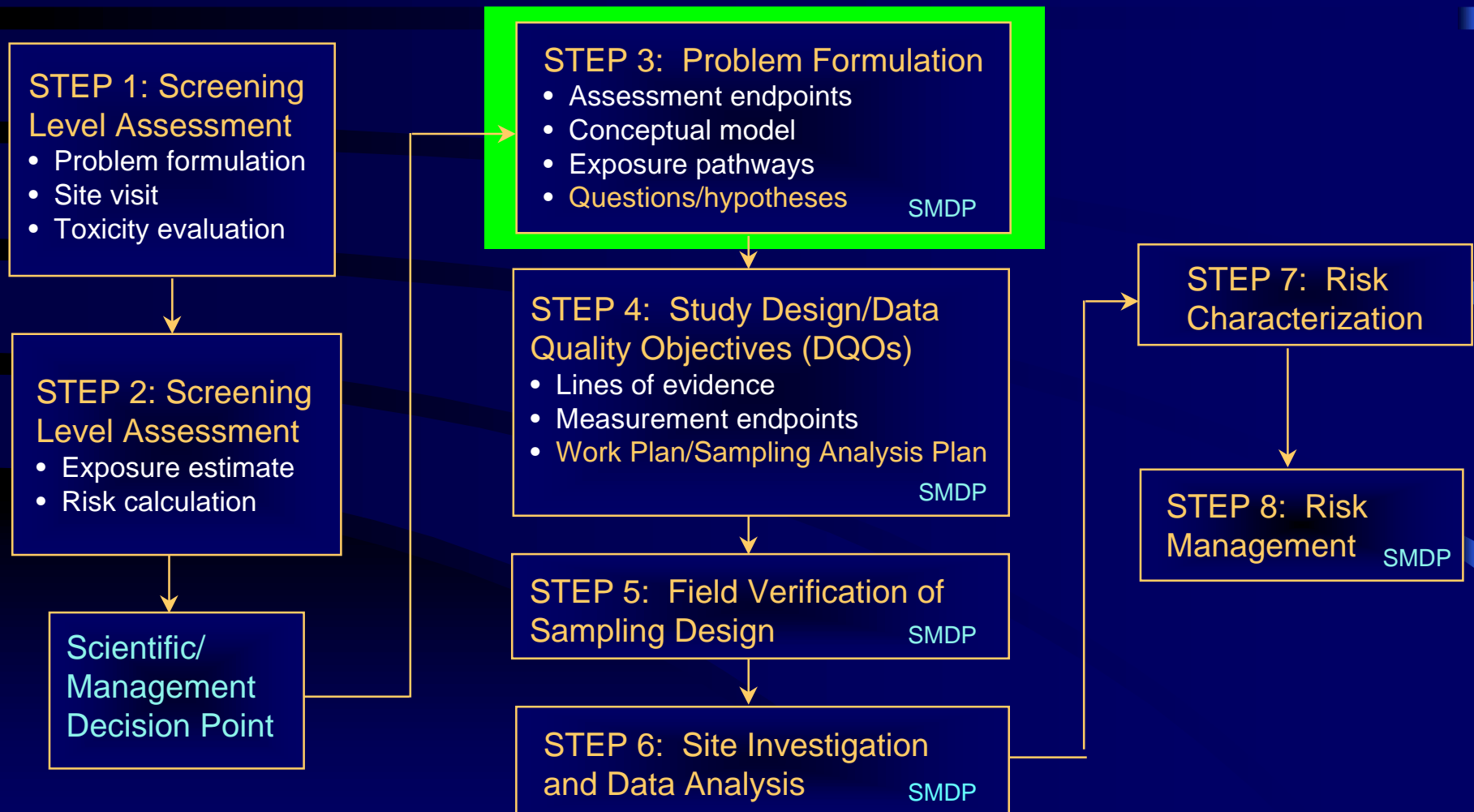
- A point during the risk assessment process when risk assessment information should be communicated to the risk manager(s) for approval.
- The risk manager(s) should determine whether the information is sufficient to arrive at a risk decision or there is a need for additional information to characterize risk.

Scientific/Management Decision Point (SMDP)

■ Is It Necessary to Continue the Ecological Risk Assessment?

- ① No, the risk is negligible
- ② More information is needed
- ③ Yes, adverse effects may result

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Step 3: Baseline Risk Assessment

Problem Formulation

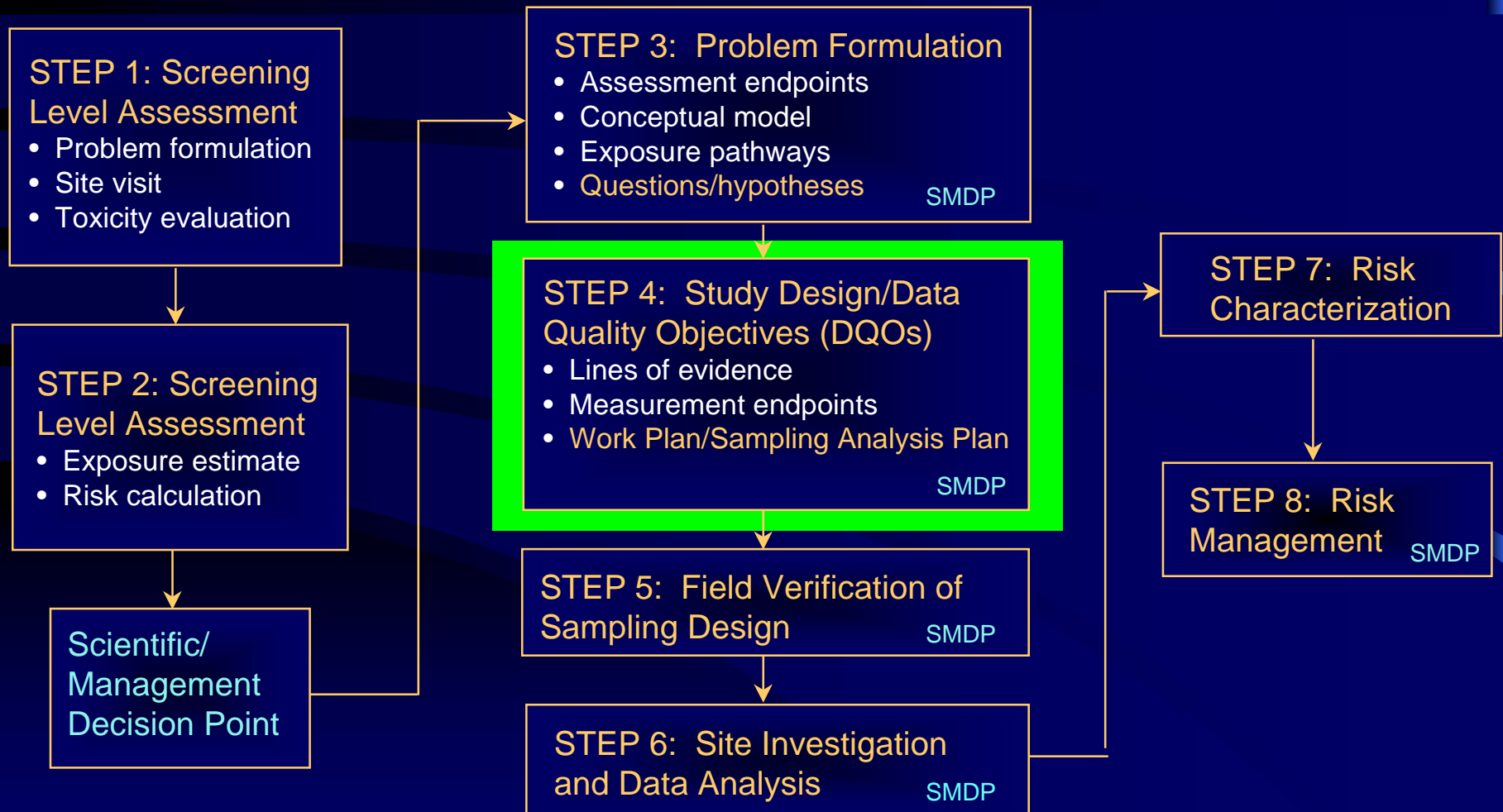
- Refinement of Preliminary Contaminants of Concern (Navy Step 3a)
- Literature Search
- Contaminant Fate and Transport
- Selection of Assessment Endpoints
- Conceptual Model and Testable Hypotheses

Step 3: Baseline Risk Assessment

SMDP

- Involved Parties Agree On:
 - ① Assessment Endpoints
 - ② Conceptual Model
 - ③ Exposure Pathways
 - ④ Questions or Risk Hypotheses

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Step 4: Study Design and Data Quality Objectives (DQOs) Process Overview

- ① Establish Measurement Endpoints
- ② Study Design
- ③ DQOs and Statistical Considerations
- ④ Work Plan and Sampling Analysis Plan

Step 4: Study Design and DQOs

Establishing Measurement Endpoints

- Species/Community/Habitat Considerations
- Relationship of the Measurement Endpoints to the Contaminant of Concern (Toxicity Mechanisms)

Step 4: Study Design and DQOs

Study Design

- Bioaccumulation and Field Tissue Residue Studies
 - Ability to accumulate the contaminant
 - Home range
 - Population size
 - Size/composites
- Population/Community Evaluations
- Toxicity Testing

Step 4: Study Design and DQOs

DQOs and Statistical Considerations

■ Data Quality Objectives

- Identify data needs
- Specify acceptable levels of decision errors

■ Statistical Considerations

- Sample approach (random or biased)
- Appropriate statistical power of the test
- Statistical models

Step 4: Study Design and DQOs

Work Plan and Sampling Analysis Plan

■ Work Plan

- Document the decisions and evaluations made during problem formulation
- Identify additional investigative tasks needed

■ Sampling Analysis Plan

- Field sampling plan
 - sample types, objectives, locations, timing, & frequency
 - sampling equipment and procedures
 - sample handling and analysis

■ Quality Assurance Project Plan (QAPP)

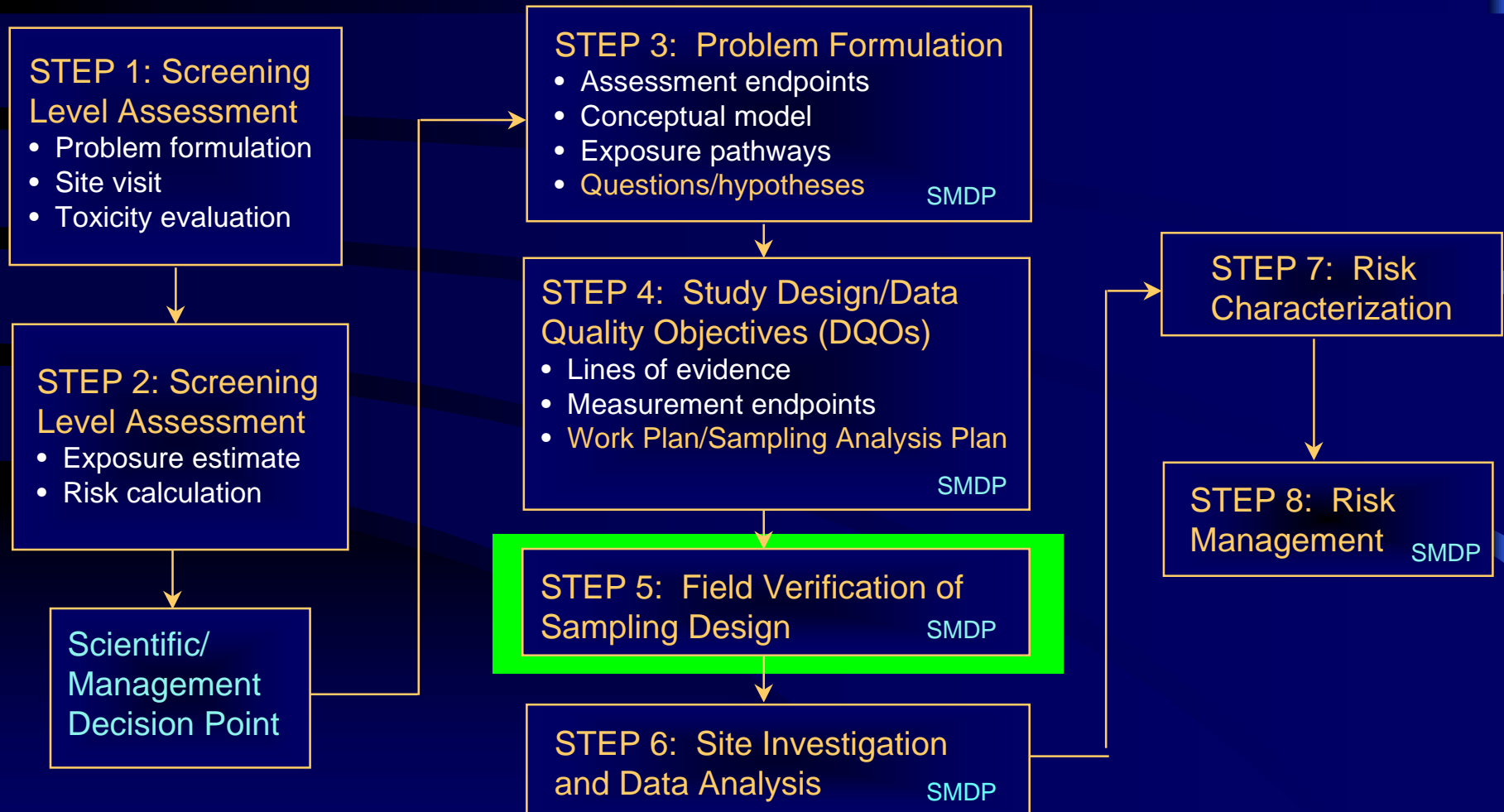
Step 4: Study Design and DQOs

SMDP

■ Verify Agreement on:

- ① Selected Measurement Endpoints
- ② Study Design
- ③ DQOs and Selected Statistical Techniques

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Step 5: Field Verification of Sampling Design

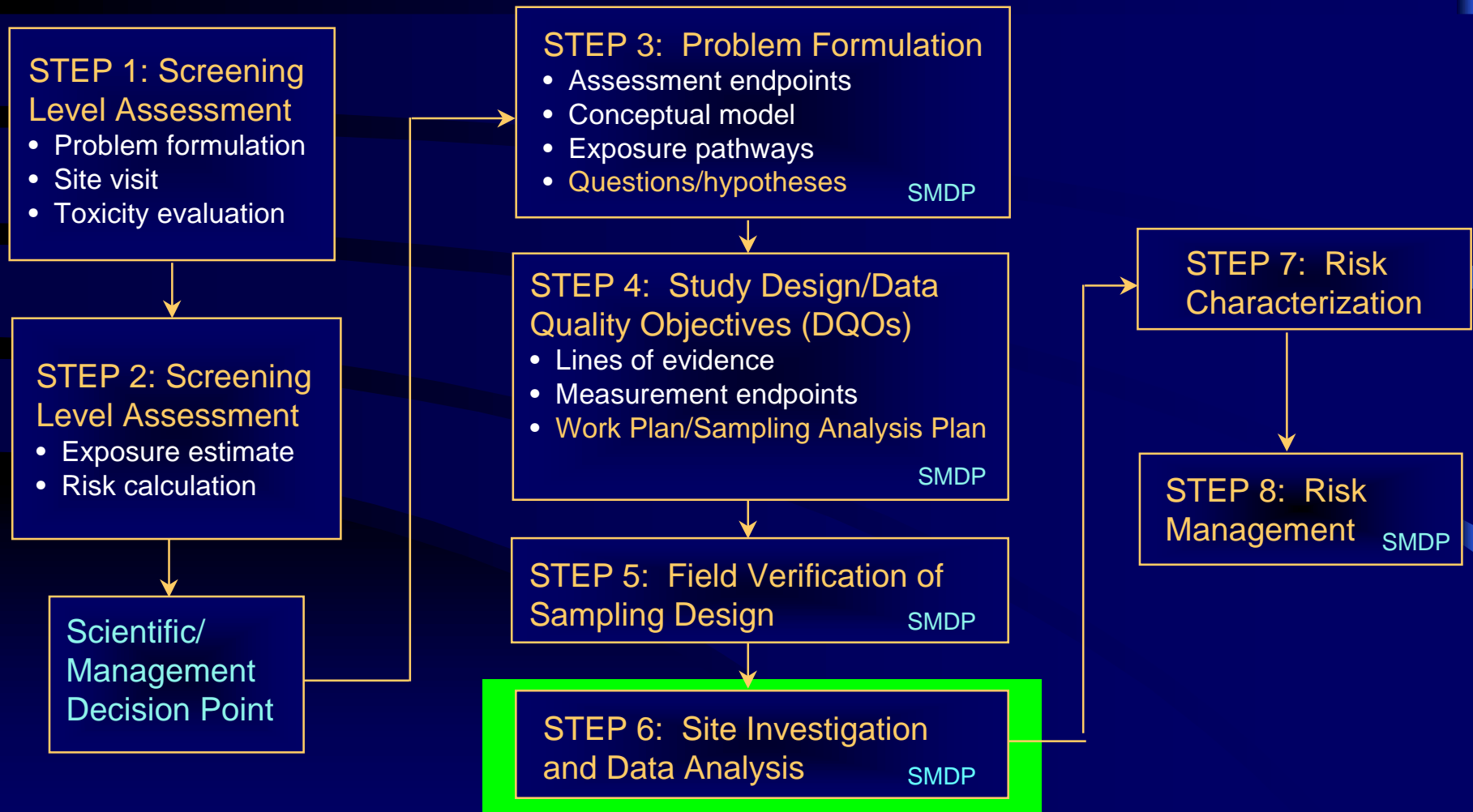
- Verify in the field that the samples specified in the Sampling Analysis Plan (SAP) are collected

Step 5: Field Verification of Sampling Design

SMDP

- All parties agree that the selected endpoints and study design are appropriate and implementable at the site

Eight-Step EPA Superfund Ecological Risk Assessment Guidance



Step 6: Site Investigation and Data Analysis

- Changing Field Conditions
- Unexpected Nature or Extent of Contamination

Step 6: Site Investigation and Data Analysis

Analysis of Ecological Exposures and Effects

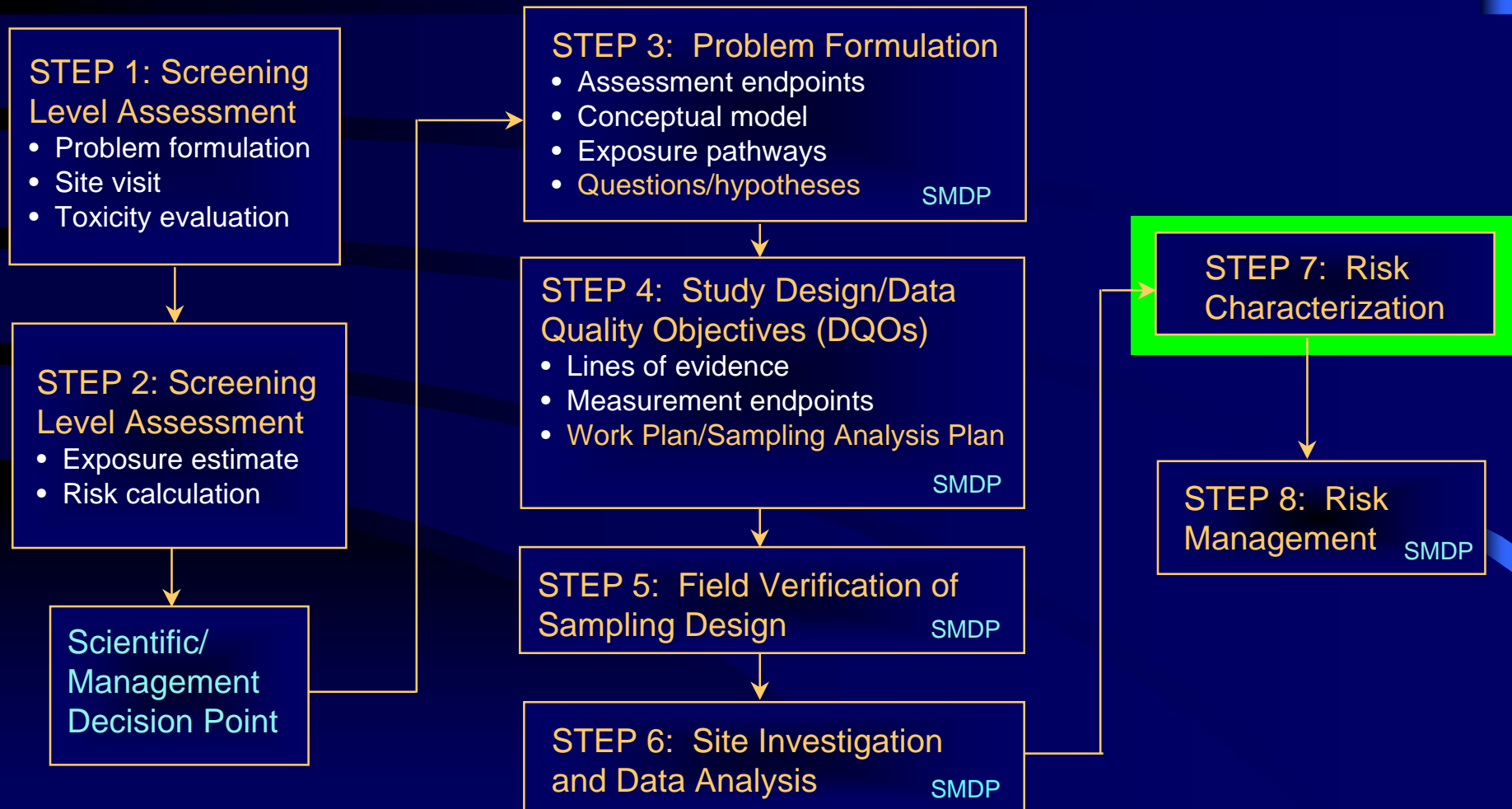
- Characterizing Exposure
- Characterizing Ecological Effects
 - Exposure-response analysis
 - Evidence of causality

Step 6: Site Investigation and Data Analysis

SMDP

- SMDP is needed if any alterations to the Work Plan or Sampling Analysis Plan become necessary

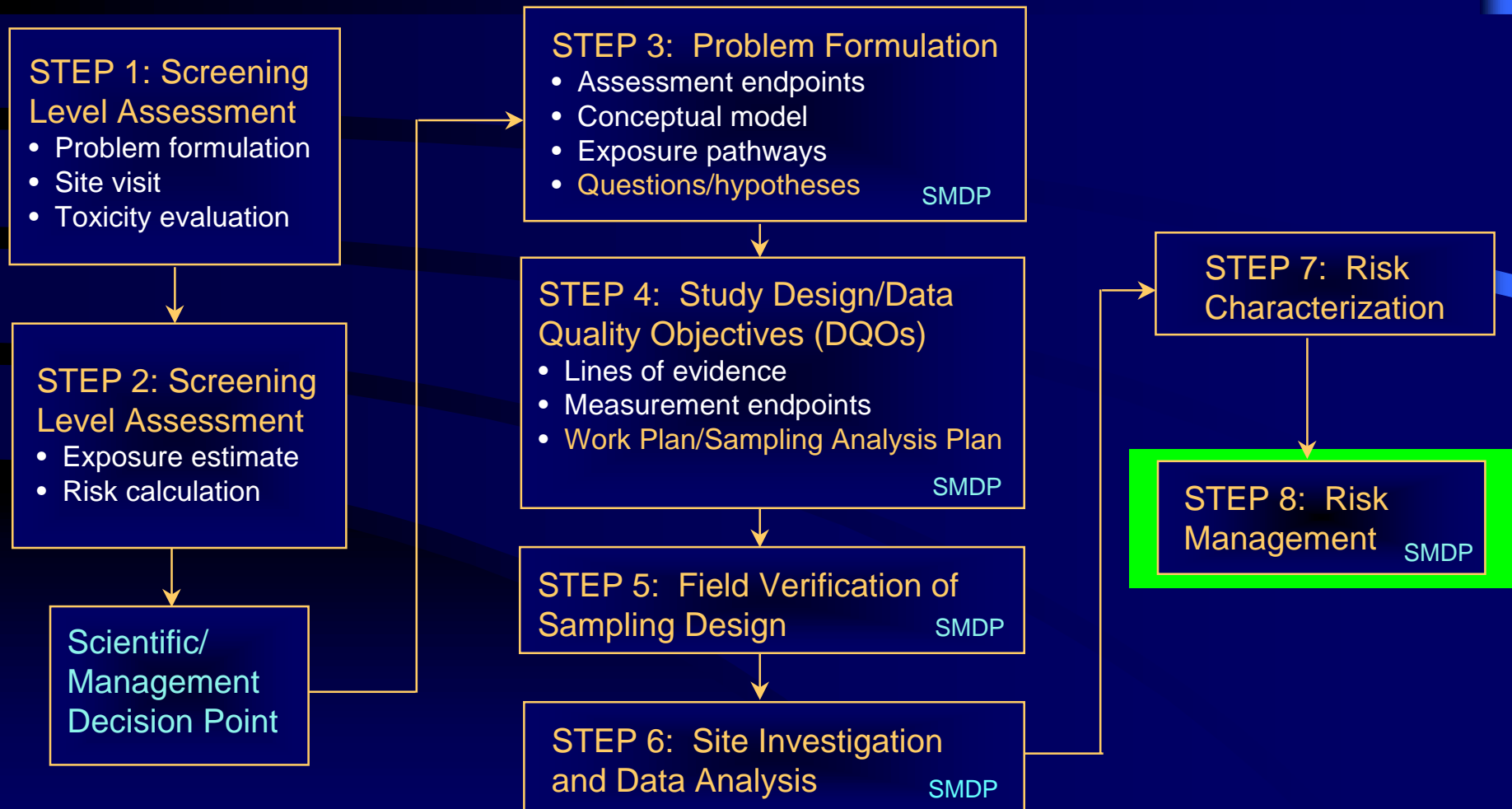
Eight-Step EPA Superfund Ecological Risk Assessment Guidance



Step 7: Risk Characterization

- Risk Estimation
- Risk Description
 - Threshold for effects on assessment endpoints
- Additional Risk Information
- Uncertainty Analysis
 - Categories of uncertainty
 - Tracking uncertainties

Eight-Step EPA Superfund Ecological Risk Assessment Guidance



Step 8: Risk Management

- Other Risk Management Considerations
- Ecological Impacts of Remedial Options
- Monitoring

Step 8: Risk Management

SMDP

- The risk management decision is finalized in the Record of Decision (ROD)

Questions?

- For Copies of EPA Guidance Document
 - <http://204.46.140.12>



Topic Overview

- EPA Eight-Step Guidance

- Navy Policy

- Case Study

■ Navy Policy

Background

- DON Environmental Policy Memorandum 97-04: Use of Ecological Risk Assessments
 - Dated 16 May 1997
- DON Policy for Conducting Ecological Risk Assessments (ERA)
 - Dated 5 April 1999
- NAVFAC Guidance Under Development

ASN Policy

■ Key Message

- Navy needs to do ERAs, but needs to do them smarter and more efficiently.



CNO Policy. Purpose

“...to provide clarification of the Navy’s policy on Ecological Risk Assessments (ERA) and the manner in which ERAs shall be implemented for Navy in the Environmental Restoration Program.”

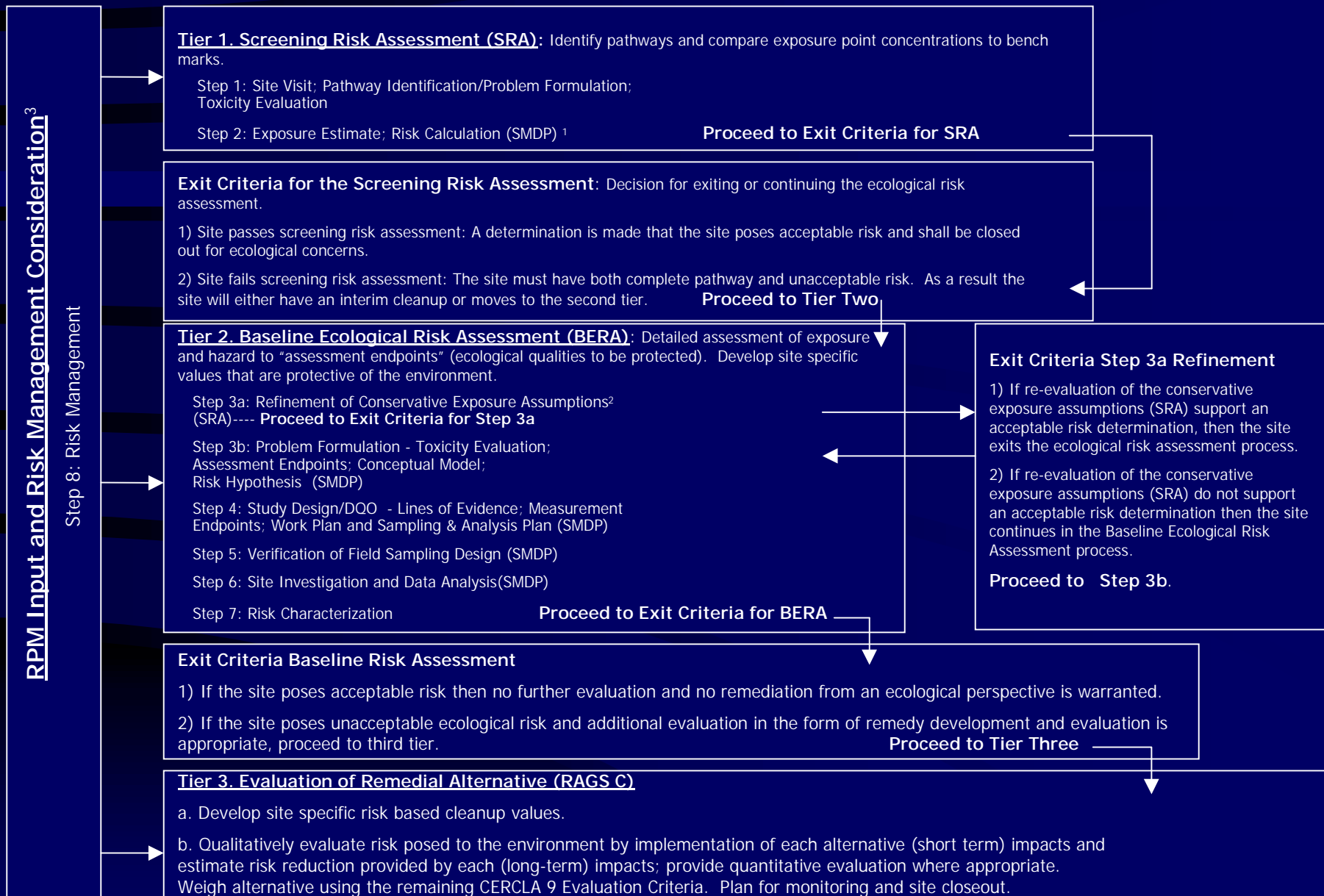
CNO Policy. Goal

- To ensure to the fullest extent possible that ERAs conducted:
 - Are scientifically based
 - Are defensible
 - Are done in a manner that is cost-effective
 - Maintain protection of the environment

CNO Policy. Details

- Fully Consistent with EPA ERA Guidance
- Three-Tiered Approach
 - Tier 1: Screening Risk Assessment (SRA)
 - Tier 2: Baseline ERA (BERA)
 - Tier 3: Evaluation of Remedial Alternatives
- Emphasizes Frequent Interactions & Concurrence with Regulators

Navy Ecological Risk Assessment Tiered Approach

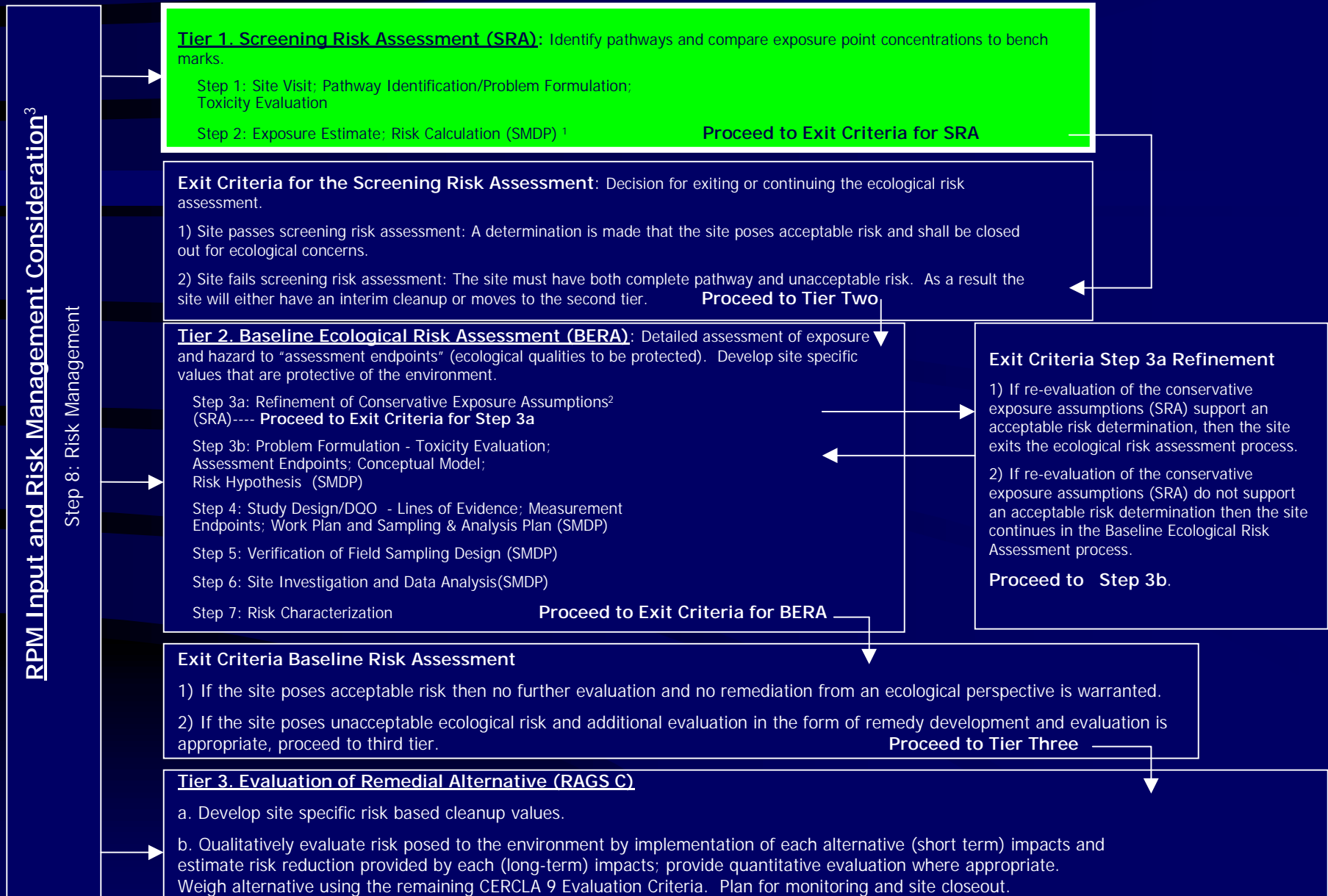


Notes: 1) See EPA's 8 Steps ERA Process for requirements for each Scientific Management Decision Point (SMDP).

2) Refinement includes but is not limited to background, bioavailability, and detection frequency.

3) Risk Management is incorporated throughout the tiered approach.

Navy Ecological Risk Assessment Tiered Approach



Notes: 1) See EPA's 8 Steps ERA Process for requirements for each Scientific Management Decision Point (SMDP).

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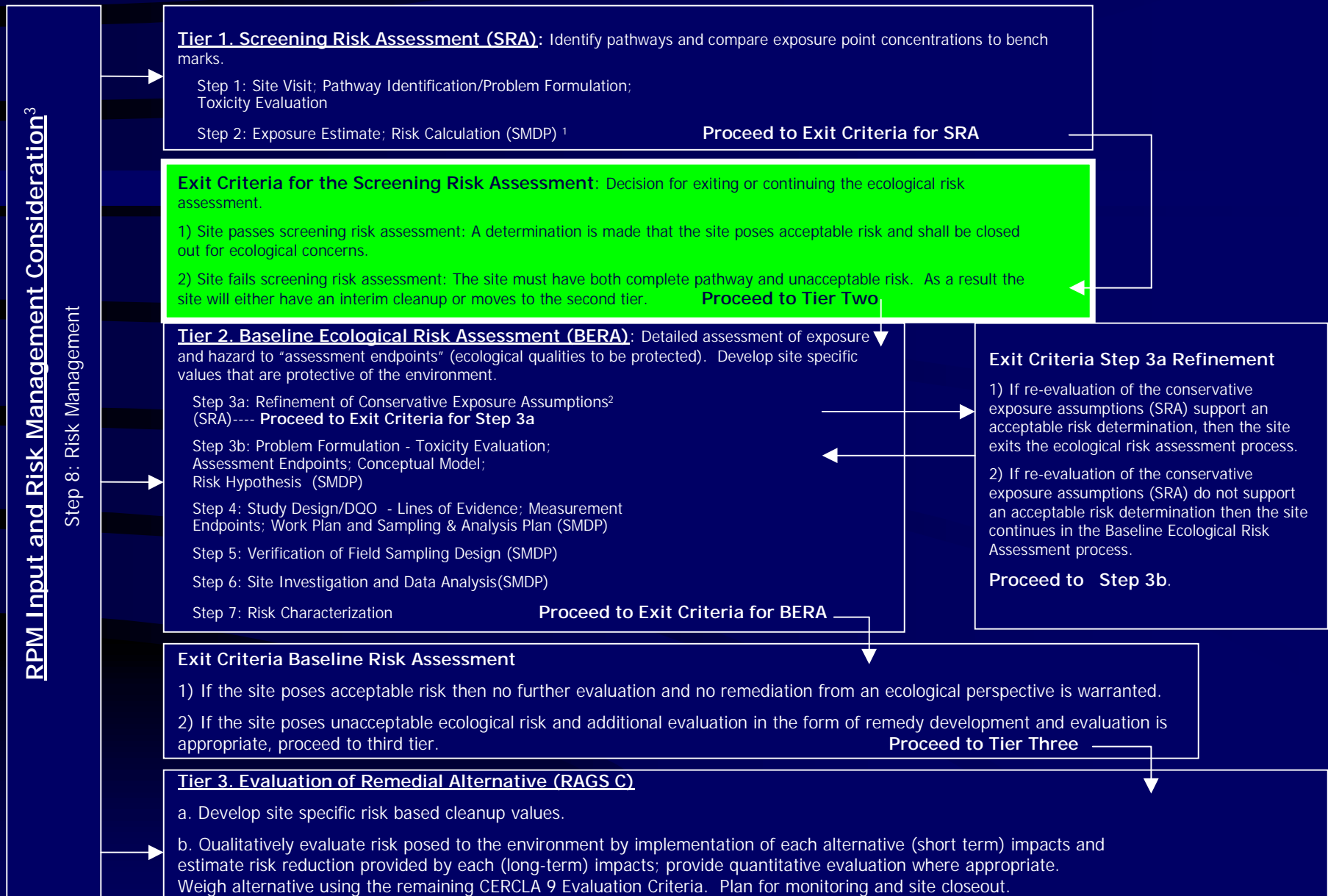
3) Risk Management is incorporated throughout the tiered approach.

Tier 1. Screening Risk Assessment (SRA)

Key Points

- Use Existing Data
- New or Additional Data not Required Unless:
 - No site data exists
 - Lack of full sweep of chemical data
- Costs Should be Low
- 2- to 3-Month Completion Time

Navy Ecological Risk Assessment Tiered Approach



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Tier 1. Screening Risk Assessment

Exit Criteria

1) Site Passes Screen:

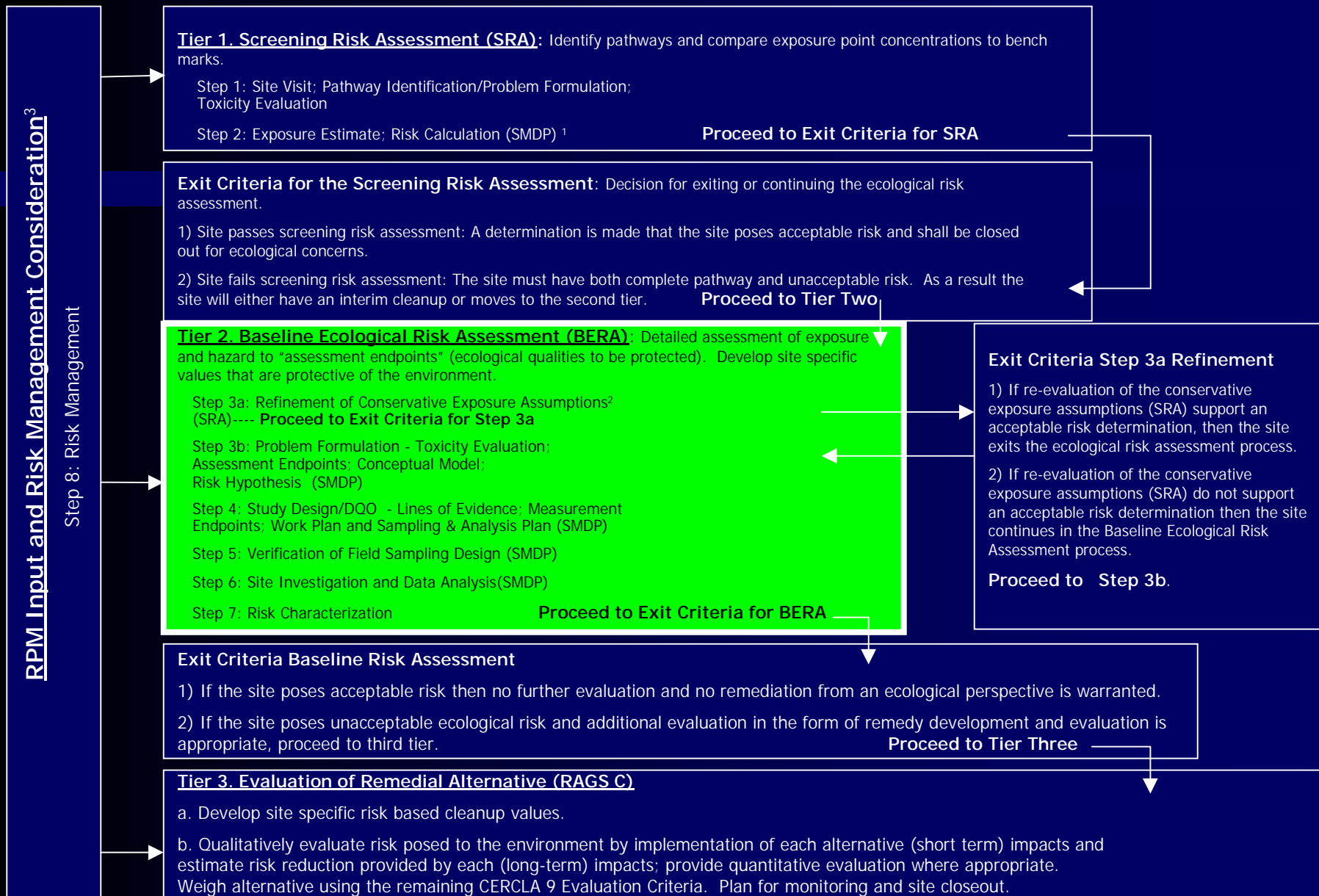
- Incomplete exposure pathway
- Absence of unacceptable risk
- Site closed for ecological concerns

2) Site Fails Screen:

- Complete exposure pathway
- Unacceptable risk
- Perform interim cleanup or move to Tier 2

3) Site Fails, but COPCs are Eliminated from Further Consideration

Navy Ecological Risk Assessment Tiered Approach



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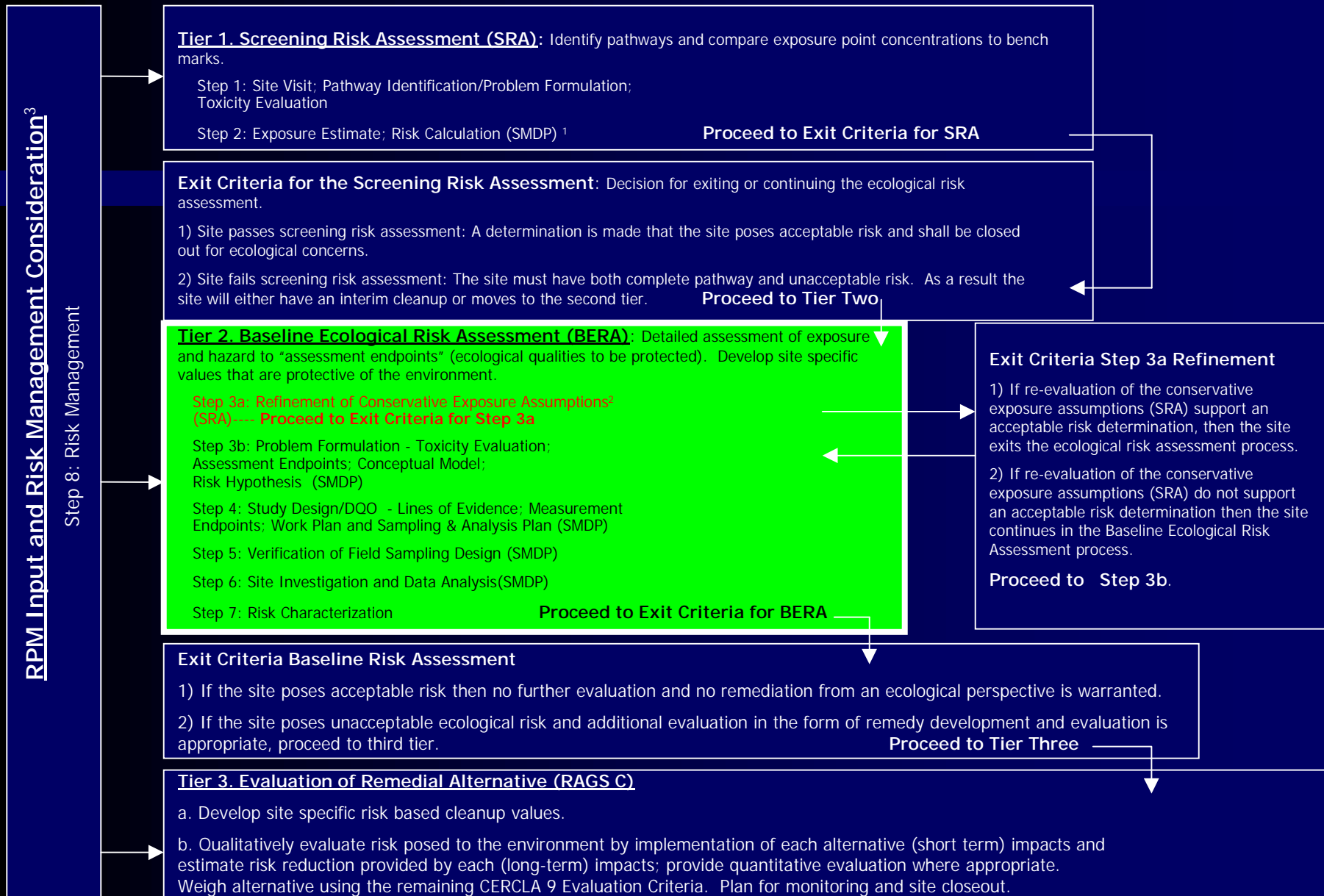
Figure 1

Tier 2. Baseline ERA

General Key Points

- More Rigorous & Less Conservative
- Further Documentation Required
- Additional Data Collection & Evaluation
- First Activity is Refinement of Exposure Assumptions (Step 3a)

Navy Ecological Risk Assessment Tiered Approach



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Figure 1

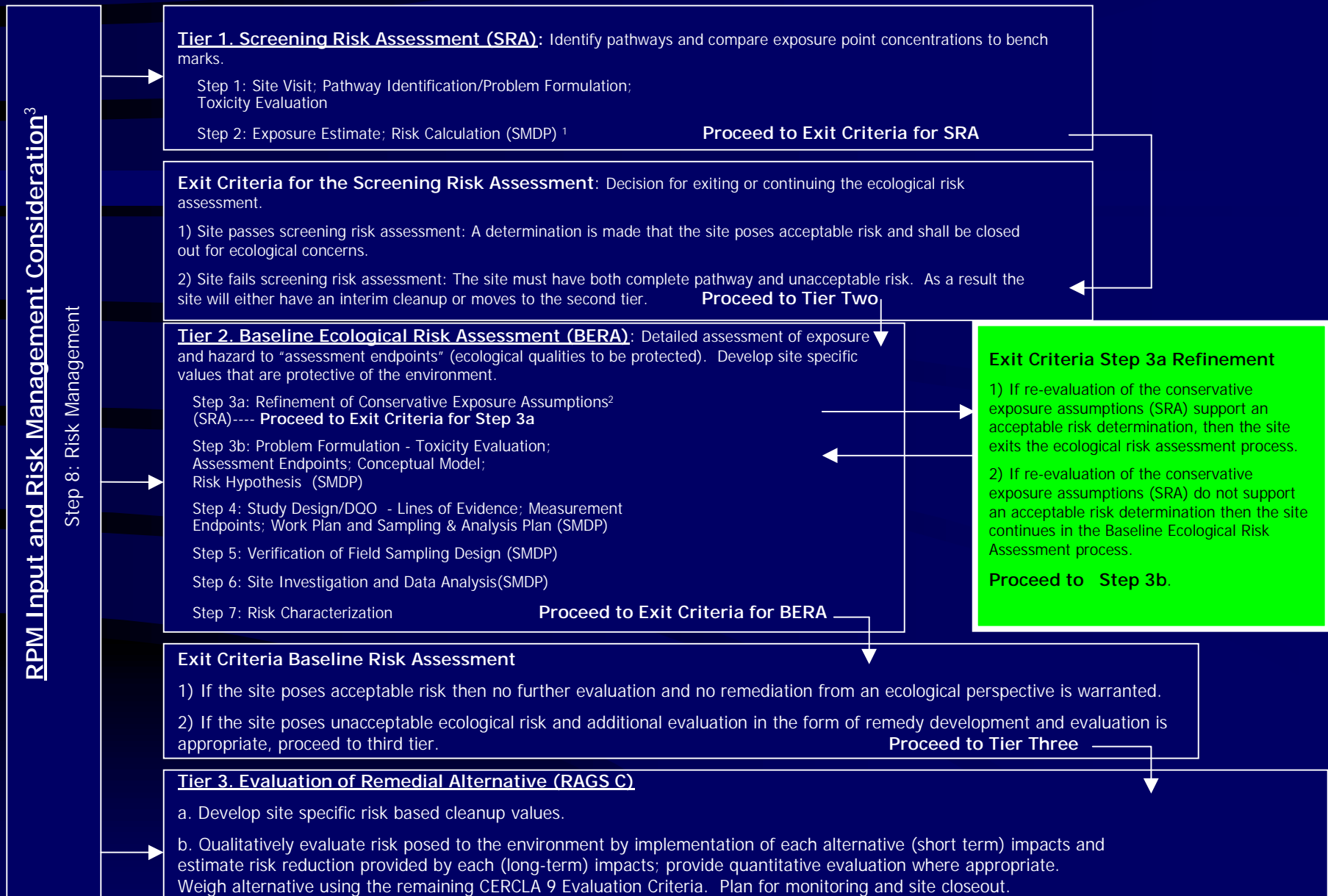
Tier 2. Baseline ERA – Step 3a

Key Points

Refinement of assumptions may include:

- Considerations of Background
- Sample Detection Frequency
- Bioavailability
- Realistic Exposure Scenarios

Navy Ecological Risk Assessment Tiered Approach



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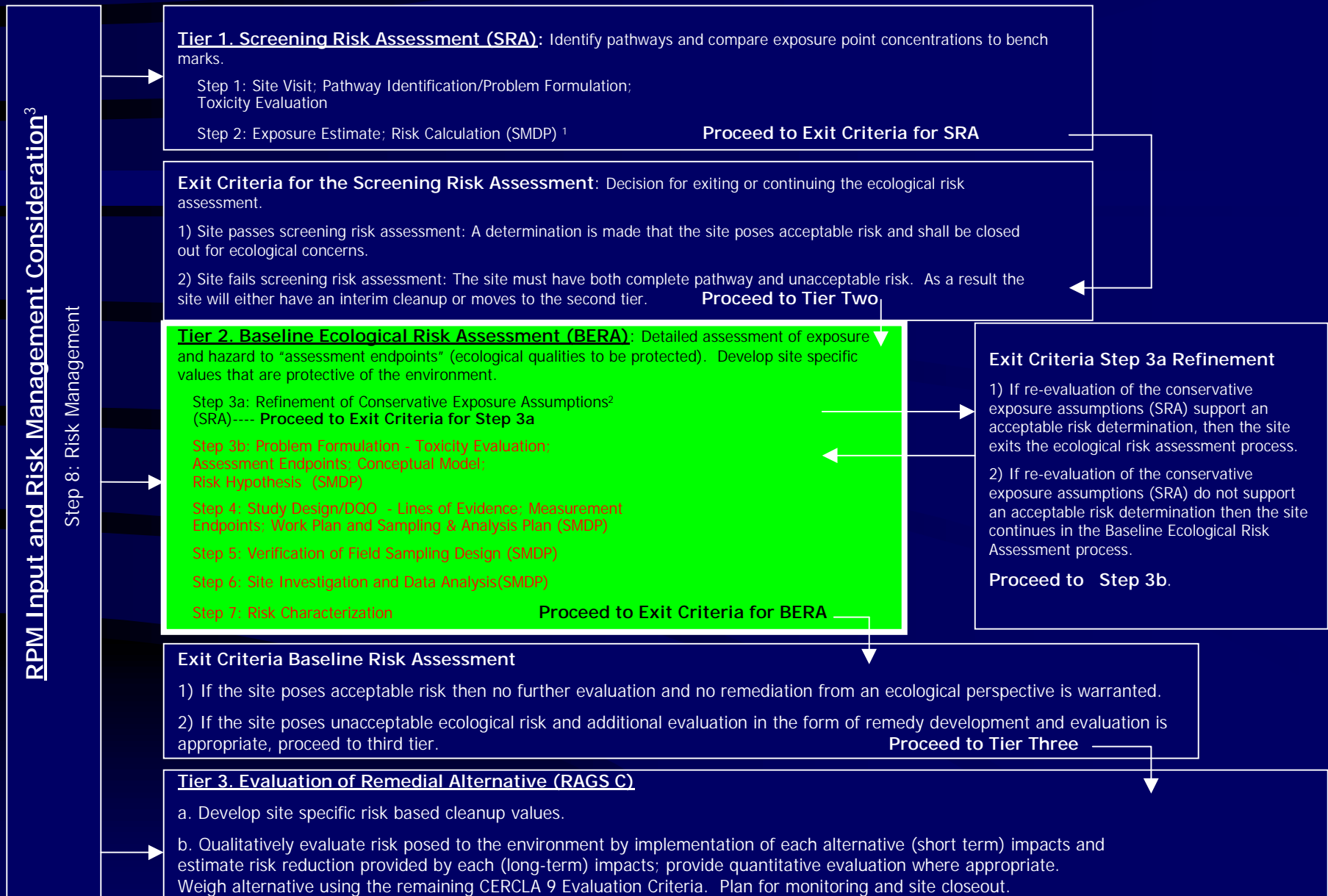
3) Risk Management is incorporated throughout the tiered approach.

Tier 2. Baseline ERA – Step 3a

Exit Criteria

- 1) Re-evaluation of data supports NFA and site exits the ERA
- 2) Re-evaluation of data continues to show unacceptable risk,
Tier 2 BERA continues

Navy Ecological Risk Assessment Tiered Approach



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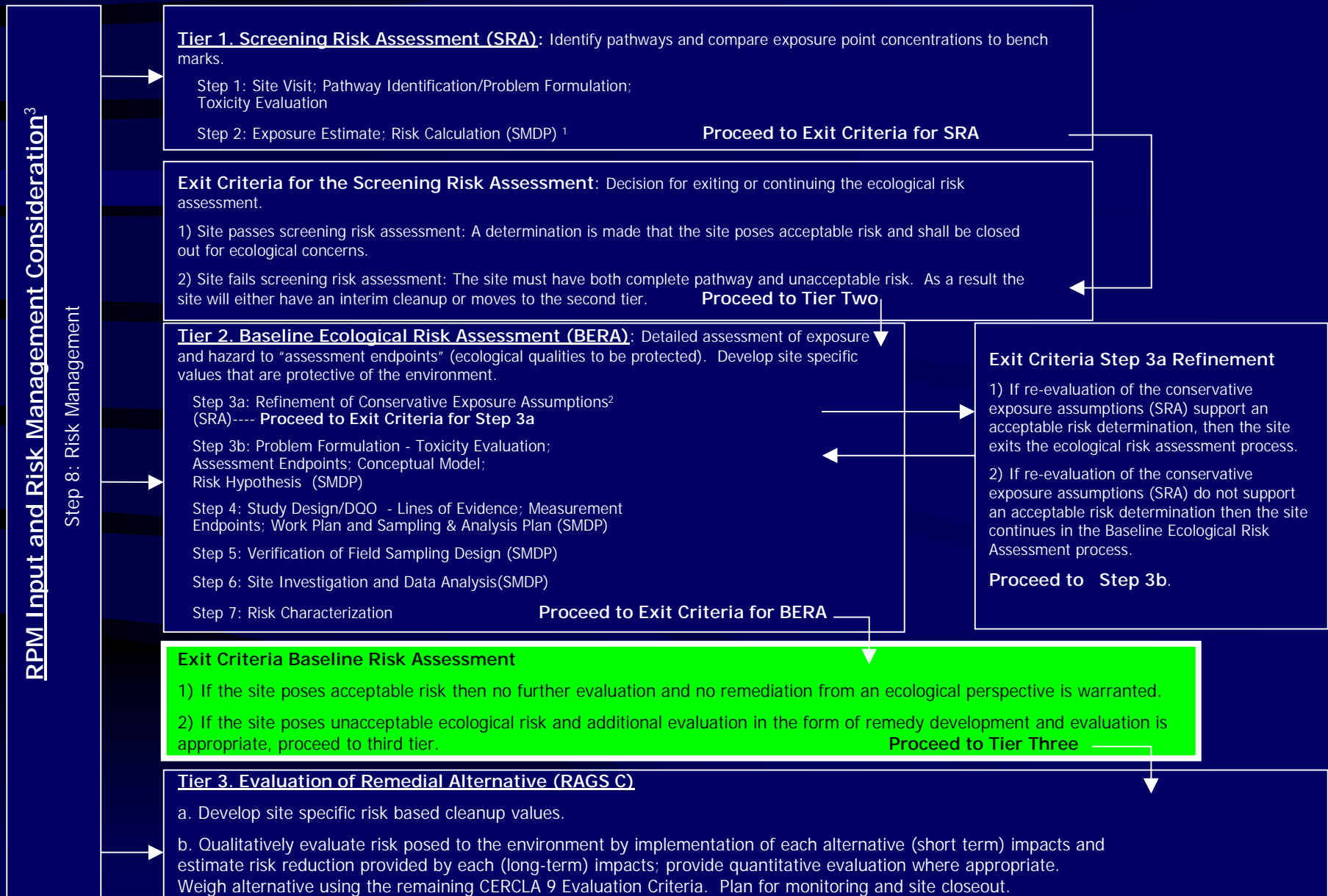
Tier 2. Baseline ERA

Key Points

RPMs must:

- Do Project Planning and Study Design/Verification (EPA Steps 3 to 5)
- Clearly Understand Their Support Contractor's Proposed ERA Work Before Moving Forward
- Communicate with and Receive Concurrence from Regulators & Stakeholders Through the SMDPs
- Document All Opposing Positions and Elevate to Navy Management in Case of Non-Concurrence

Navy Ecological Risk Assessment Tiered Approach



Notes: 1) See EPA's 8 Steps ERA Process for requirements for each Scientific Management Decision Point (SMDP).

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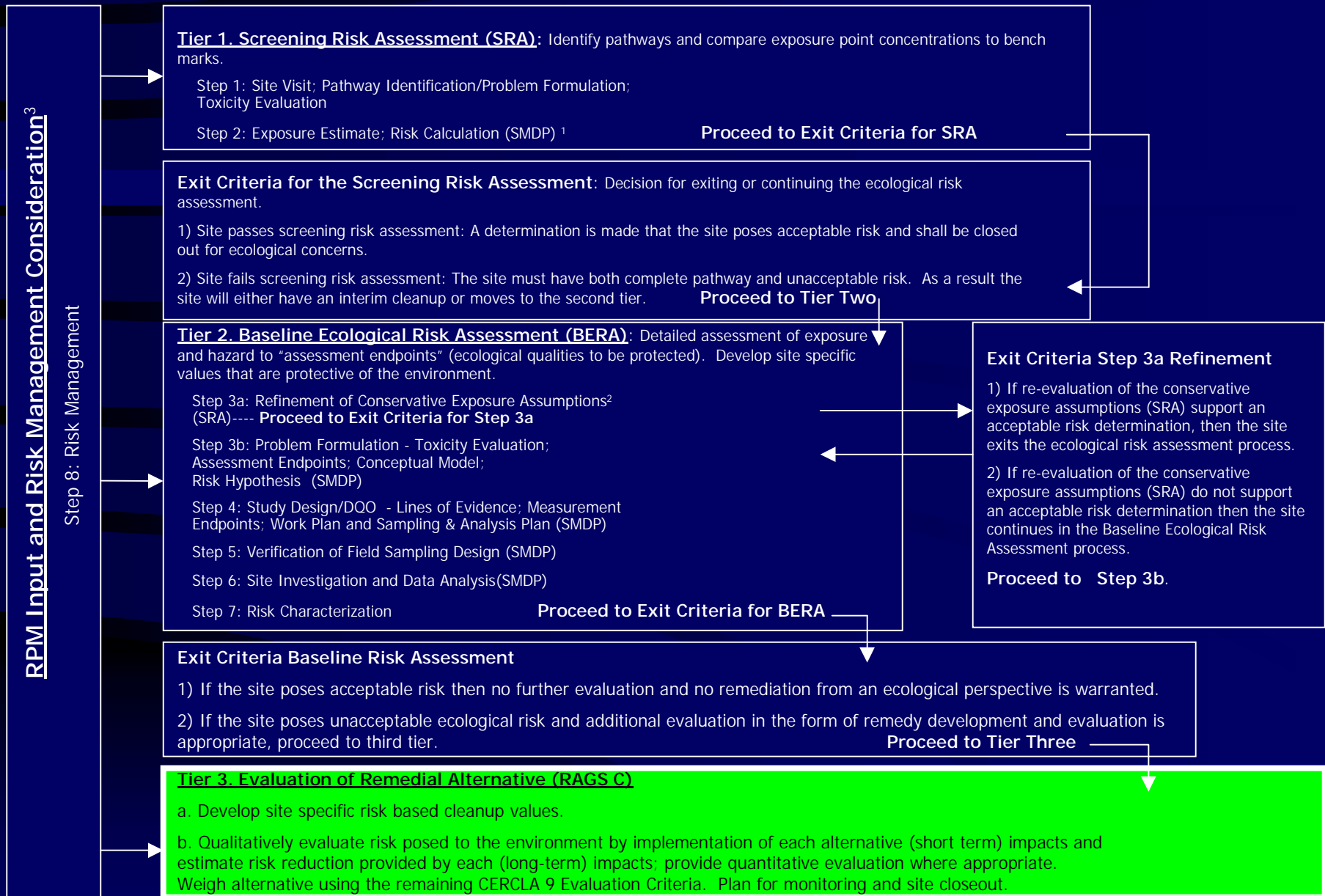
Tier 2. Baseline ERA

Exit Criteria

RPM empowered to make one of the following risk management decisions:

- 1) NFA from ecological perspective
or
- 2) Site poses unacceptable ecological risk and evaluation of remedies is warranted – move to Tier 3

Navy Ecological Risk Assessment Tiered Approach



Notes: 1) See EPA's 8 Steps ERA Process for requirements for each Scientific Management Decision Point (SMDP).

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3) Risk Management is incorporated throughout the tiered approach.

Tier 3. Evaluation of Remedial Alternatives

The purpose of Tier 3 is to ensure that remedial alternatives are adequately evaluated from an ecological perspective, so that the outcome of the remediation is not more detrimental to the environment than if the site had not been remediated.

Tier 3. Evaluation of Remedial Alternatives

Key Points

At Tier 3 conclusion, should have identified for each alternative:

- Effectiveness at Reducing Risk
- Potential Environmental Impacts
- Residual Risk
- Cost (\$)
- Technical Merits & Benefits
- Acceptance by Navy & Stakeholders

Navy Ecological Risk Assessment Tiered Approach

RPM Input and Risk Management Consideration³

Step 8: Risk Management

Tier 1. Screening Risk Assessment (SRA): Identify pathways and compare exposure point concentrations to bench marks.

Step 1: Site Visit; Pathway Identification/Problem Formulation; Toxicity Evaluation

Step 2: Exposure Estimate; Risk Calculation (SMDP) ¹

Proceed to Exit Criteria for SRA

Exit Criteria for the Screening Risk Assessment: Decision for exiting or continuing the ecological risk assessment.

1) Site passes screening risk assessment: A determination is made that the site poses acceptable risk and shall be closed out for ecological concerns.

2) Site fails screening risk assessment: The site must have both complete pathway and unacceptable risk. As a result the site will either have an interim cleanup or moves to the second tier.

Proceed to Tier Two

Tier 2. Baseline Ecological Risk Assessment (BERA): Detailed assessment of exposure and hazard to "assessment endpoints" (ecological qualities to be protected). Develop site specific values that are protective of the environment.

Step 3a: Refinement of Conservative Exposure Assumptions² (SRA)---- **Proceed to Exit Criteria for Step 3a**

Step 3b: Problem Formulation - Toxicity Evaluation; Assessment Endpoints; Conceptual Model; Risk Hypothesis (SMDP)

Step 4: Study Design/DOO - Lines of Evidence; Measurement Endpoints; Work Plan and Sampling & Analysis Plan (SMDP)

Step 5: Verification of Field Sampling Design (SMDP)

Step 6: Site Investigation and Data Analysis(SMDP)

Step 7: Risk Characterization

Proceed to Exit Criteria for BERA

Exit Criteria Step 3a Refinement

1) If re-evaluation of the conservative exposure assumptions (SRA) support an acceptable risk determination, then the site exits the ecological risk assessment process.

2) If re-evaluation of the conservative exposure assumptions (SRA) do not support an acceptable risk determination then the site continues in the Baseline Ecological Risk Assessment process.

Proceed to Step 3b.

Exit Criteria Baseline Risk Assessment

1) If the site poses acceptable risk then no further evaluation and no remediation from an ecological perspective is warranted.

2) If the site poses unacceptable ecological risk and additional evaluation in the form of remedy development and evaluation is appropriate, proceed to third tier.

Proceed to Tier Three

Tier 3. Evaluation of Remedial Alternative (RAGS C)

a. Develop site specific risk based cleanup values.

b. Qualitatively evaluate risk posed to the environment by implementation of each alternative (short term) impacts and estimate risk reduction provided by each (long-term) impacts; provide quantitative evaluation where appropriate. Weigh alternative using the remaining CERCLA 9 Evaluation Criteria. Plan for monitoring and site closeout.

Notes: 1) See EPA's 8 Steps ERA Process for requirements for each Scientific Management Decision Point (SMDP).

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3) Risk Management is incorporated throughout the tiered approach.

RPM Input and Risk Management Considerations (Step 8)

- Risk Management Considerations are Incorporated Throughout the Tiered Approach

Natural Resources

"If there are natural resources potentially impacted by Navy releases, then involve proper trustees during the ecological risk assessment process, to the extent practicable. Trustee involvement is encouraged in our cleanup program, but Navy is the lead agency and the Navy and appropriate parties (i.e., regulators only) shall make all final decisions."

Existing Ecological Risk Assessments

"Baseline ecological risk assessments that are already underway should meet the substantive requirements of Tiers 1, 2, and 3."

Value Added by the Tiers

- Clarifies the EPA Process
- Clearly Identifies Exit Points
 - Don't have to do all eight steps
- Emphasizes EPA's Initial Step 3 Effort
 - Refines the assumptions & PCOC list
- Helps Focus the ERA
 - Emphasizes the screen first
- Mirrors Human Health Risk Assessment Process

Recommendations

- When talking to regulators, clearly link the EPA eight-step process with the Navy tiers
- Reflect each of EPA's eight steps within the ERA design
- Do not skip the SMDPs
- Document the outcome of the SRA and Step 3a
- Important to do the planning up front (EPA Steps 3 to 5) before jumping into data collection

ERA SOW Template

- Defines Contractor Requirements in Accordance with Navy Policy and EPA Guidance
- Identifies Deliverables by Step

NAVY ERTAT

- Centrally Funded So No Cost to RPMs
- Team Members:
 - NFESC as Team Coordinator
 - EPA ERT as primary technical support
 - SSC for sediment-specific sampling and analytical support
- Available Support
 - Technical guidance on ERA scoping and designs
 - Review of contractor ERA workplans and reports
 - Technical strategies to meet local regulatory concerns

Point of Contact

■ Ruth Owens

- Phone: (805) 982-4798, DSN 551-4798
- Fax: (805) 982-4303, DSN 551-4303
- E-mail: rowens@nfesc.navy.mil

Or

■ Your Local TSR

Topic Overview

- EPA Eight-Step Guidance

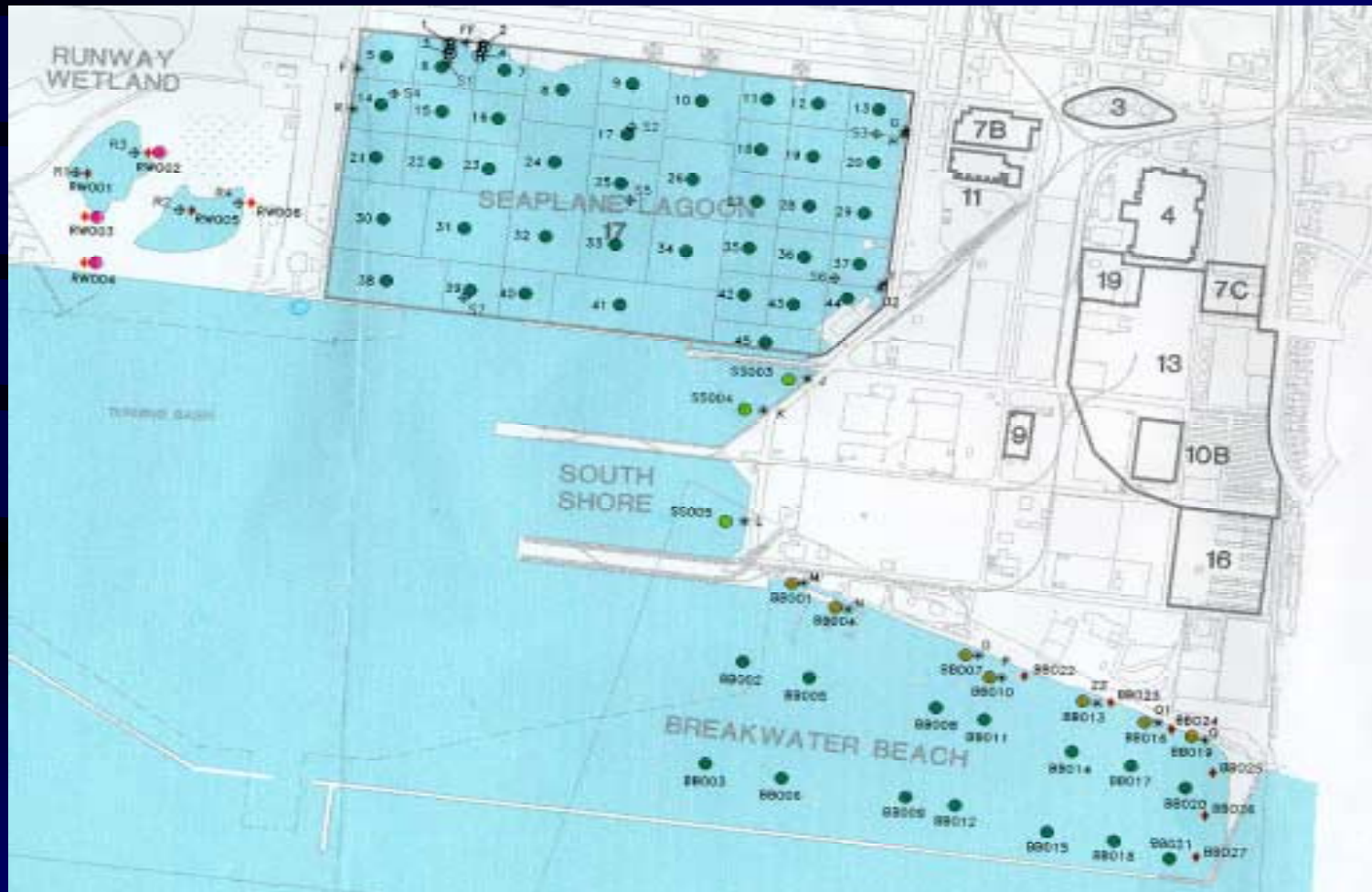
- Navy Policy

- Case Study

■ Case Study

Seaplane Lagoon ERA Case Study

Site Map



Site History

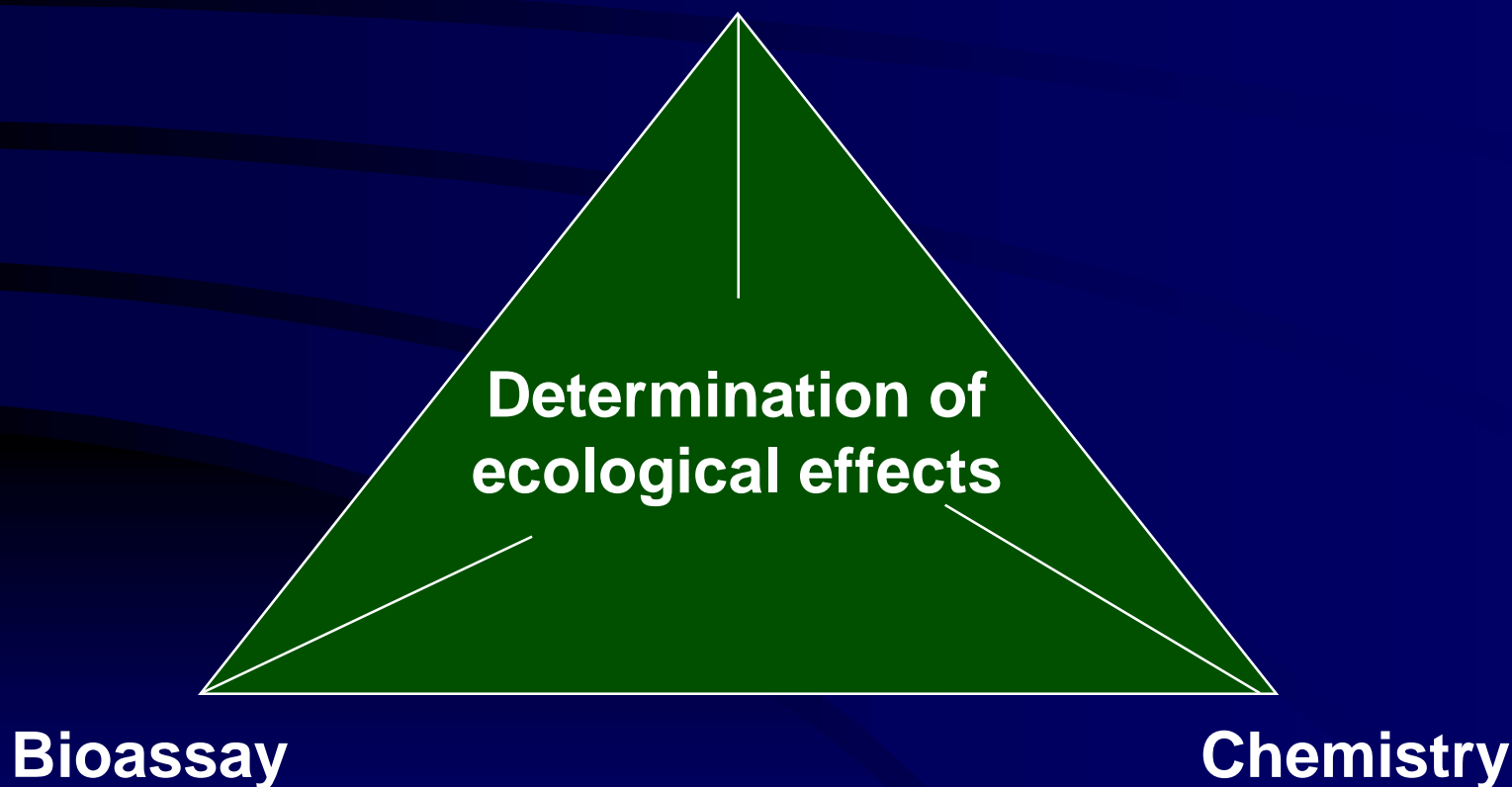
- Built as a Seaplane Lagoon in the 1940s
- Plating Shop and Other Industrial Waste Discharged, via Storm and Sewer, from 1940s to Early 1970s
- BRAC Facility
 - Potential reuse is a city marina

ERA History

- In early 1990s, metals and chlorinated hydrocarbons were detected at the site
- Some early bioassays indicated toxicity, but cause was uncertain
- 1996 study conducted for nature and extent
- 1997 study (results pending) attempted to show correlation between toxicity, concentration, and bioaccumulation in tissue and sediment concentrations
 - Data suggest that the metals and PCBs may not be available due to reburial or sediment chemistry

Benthic Triad Approach

Benthic Community Structure



ERA Issues

- Regulatory perception is that site is very toxic, but the data do not support this
- Perceived broken promises and miscommunication has led to regulatory distrust in Navy efforts
- Unclear conceptual model has led regulators to believe Navy was ignoring important parts of the food web, including humans

ERA Solution

- EFA West Project Team brought in a DQO facilitator and the ERTAT to help clarify the ERA
- Developed matrix table for each assessment endpoint
 - Shows problem formulation & measurement endpoint development
 - Rationale for selections of endpoints

Matrix Table of Conceptual Model and Endpoints

- Receptor Class and Specific Receptors
- Assessment Endpoint
- Risk Question(s)
- Surrogate Species or Community
- Measurement Endpoint(s)
- Uncertainties
- Notes

Advantages to the Matrix Table

- Shows clear links between risk questions and selected endpoints
- Identifies uncertainties associated with selected tests
- Summarizes conceptual model in a way that allows for clear, open technical discussions
- Easy for regulators to agree or disagree with specific approach
- Helps clarify data uses and identifies data gaps as well as data overlaps

Conclusions

■ Use of this Matrix Table has:

- Helped identify the key data gaps needed to begin concluding the ERA and moving toward a remedial decision
- Helped the Navy obtain regulatory concurrence on the required remaining efforts
- Helped show that the required removal effort may be much less than previously thought necessary by all parties

In Summary

Development of this matrix approach to the Seaplane Lagoon site has led to open and clear communication based on DQOs and the EPA eight-step ERA process, which has helped move the project forward with regulatory buy-in on the proposed Navy efforts.

Where We Are Now

- Table presented. Regulators agreed with the approach.
- Currently negotiating risk characterization and interpretation techniques
- Running dose models
- Evaluate 1998 data set in summer

References

- Charters, D.W. and Sprenger, M.D. 1997. *Ecological Risk Assessment (ERA) Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessment*. EPA 540/R-97/006. U.S. EPA, Environmental Response Team.
- Navy Policy for Conducting Ecological Risk Assessments. CNO 5 Apr 99.

Scientific/Management Decision Point (SMDP)

Paraphrased from the guidance:

A point during the risk assessment process when the risk assessor communicates results of the assessment at that stage to the risk manager. At this point, the risk manager determines whether the information is sufficient to arrive at a decision regarding risk management strategies and/or the need for additional information to characterize risk.

Photos

- Photos
- This slide was previously number 76

Conceptual Model – Food Web

- Add diagram of food model that goes with the matrix table (This slide was previously number 82)